PHYSICIANS' BELIEFS AND BEHAVIOUR DURING A RANDOMIZED CONTROLLED TRIAL OF EPISIOTOMY: CONSEQUENCES FOR WOMEN IN THEIR CARE

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Abstract • Résumé

Objective: To evaluate whether physicians' beliefs concerning episiotomy are related to their use of procedures and to differential outcomes in childbirth.

Design: Post-hoc cohort analysis of physicians and patients involved in a randomized controlled trial of episiotomy.

Setting: Two tertiary care hospitals and one community hospital in Montreal.

Participants: Of the 703 women at low risk of medical or obstetric problems enrolled in the trial we studied 447 women (226 primiparous and 221 multiparous) attended by 43 physicians. Subjects attended by residents or nurses were excluded.

Main outcome measures: Patients: intact perineum v. perineal trauma, length of labour, procedures used (instrumental delivery, oxytocin augmentation of labour, cesarean section and episiotomy), position for birth, rate of and reasons for not assigning women to a study arm, postpartum perineal pain and satisfaction with the birth experience; physicians: beliefs concerning episiotomy.

Results: Women attended by physicians who viewed episiotomy very unfavourably were more likely than women attended by the other physicians to have an intact perineum (23% v. 11% to 13%, $p < 0.05$) and to experience less perineal trauma. The first stage of labour was 2.3 to 3.5 hours shorter for women attended by physicians who viewed episiotomy favourably than for women attended by physicians who viewed episiotomy very unfavourably ($p < 0.05$ to < 0.01), and the former physicians were more likely to use oxytocin augmentation of labour. Physicians who viewed episiotomy more favourably failed more often than those who viewed the procedure very unfavourably to assign patients to a study arm late in labour (odds ratio [OR] 1.88, $p < 0.05$), both overall and because they felt that "fetal distress" or cesarean section necessitated exclusion of the subject. They used the lithotomy position for birth more often (OR 3.94 to 4.55, $p < 0.001$), had difficulty limiting episiotomy in the restricted-use arm of the trial and diagnosed fetal distress and perineal inadequacy more often than the comparison groups. The patients of physicians who viewed episiotomy very favourably experienced more perineal pain ($p < 0.01$), and of those who viewed episiotomy favourably and very favourably experienced less satisfaction with the birth experience ($p < 0.01$) than the patients of physicians who viewed the procedure very unfavourably.

Conclusions: Physicians with favourable views of episiotomy were more likely to use techniques to expedite labour, and their patients were more likely to have perineal trauma and to be less satisfied with the birth experience. This evidence that physician beliefs can influence patient outcomes has both clinical and research implications.

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Objectif : Évaluer s'il y a un lien entre ce que les médecins pensent de l'épisiotomie, l'utilisation qu'ils font de l'intervention et les résultats différentiels à la naissance.

Conception : Analyste postérieure de cohortes de médecins et de patientes participant à une étude contrôlée et randomisée sur l'épisiotomie.

Contexte : Deux hôpitaux de soins tertiaires et un hôpital communautaire de Montréal.

Participants : Sur les 703 femmes à faible risque de problèmes médicaux ou obstétriques qui ont participé à l'étude, on a étudié le cas de 447 femmes (226 primipares et 221 multipares) traitées par 43 médecins. Les femmes traitées par des résidents ou des infirmières ont été exclues.

Principales mesures des résultats : Patientes : périnée intact c. traumatisme périnéal, durée du travail, interventions pratiquées (accouchement dirigé, accélération du travail à l'oxytocine, césarienne et épisiotomie), position pour la naissance, taux des femmes qui n'ont pas été affectées à un volet de l'étude et motifs de la non-affectation, douleur périnéale après l'accouchement et satisfaction face à l'expérience de la naissance; médecins : ce qu'ils pensent de l'épisiotomie.

Résultats : Les femmes traitées par des médecins très défavorables à l'épisiotomie étaient plus susceptibles que les femmes traitées par les autres médecins d'avoir un périnée intact (23 % c. 11 % à 13 %, $p < 0,05$) et de subir moins de traumatisme périnéal. Le premier stade du travail a duré de 2,3 à 3,5 heures de moins chez les femmes traitées par un médecin favorable à l'épisiotomie que chez les femmes traitées par un médecin très défavorable à l'épisiotomie ($p < 0,05$ à $< 0,01$). Dans le dernier cas, les médecins étaient plus susceptibles d'accélérer le travail en utilisant de l'oxytocine. Les médecins plus favorables à l'épisiotomie ont évité plus souvent que ceux qui y étaient très défavorables d'affecter les patientes à un volet de l'étude vers la fin du travail (ratio des probabilités [RP] 1,88, $p < 0,05$), à la fois dans l'ensemble et parce qu'ils croyaient qu'il fallait exclure le sujet à cause de la «souffrance fœtale» ou d'une césarienne. Ils ont utilisé la position gynécologique pour la naissance plus souvent (RP 3,94 à 4,55, $p < 0,001$), ont eu de la difficulté à limiter l'épisiotomie au volet d'utilisation limitée de l'étude et diagnostiqué une souffrance fœtale et une insuffisance périnéale plus souvent que dans le cas des groupes de comparaison. Les patientes des médecins très favorables à l'épisiotomie ont eu plus de douleurs périnéales ($p < 0,01$) et celles des médecins favorables et très favorables à l'épisiotomie ont été moins satisfaites de l'expérience de la naissance ($p < 0,01$) que les patientes de ceux qui étaient très défavorables à l'intervention.

Conclusions : Les médecins favorables à l'épisiotomie étaient plus susceptibles d'accélérer le travail et leurs patientes étaient plus susceptibles de subir des traumatismes du périnée et d'être moins satisfaites de l'expérience de la naissance. Cela démontre que ce que pensent les médecins peut avoir un effet sur les résultats des patients, ce qui a des répercussions à la fois sur les aspects cliniques et sur la recherche.

In our randomized controlled trial of episiotomy[1,2] we compared a policy of restricting episiotomy use to specified fetal and maternal indications with the routine or liberal use that characterizes most of North American practice. The study involved 703 comparable women at low risk of medical or obstetric problems, who were followed for 3 months post partum. Among the primiparous women we found similar rates of overall perineal trauma in the two groups, with more trauma caused by episiotomy in the liberal-use group and more spontaneous tears in the restricted-use group. However, among multiparous women, those in the restricted-use group gave birth with an intact perineum more often than those in the liberal-use group. All but one of the 53 third- and fourth-degree perineal tears were associated with median episiotomy. No differences in postpartum perineal pain, perineal muscle strength (as assessed by means of electromyographic perineometry) before birth and 3 months post partum, urinary and pelvic-floor symptoms or sexual functioning were found between the trial groups. Women with an intact perineum had less perineal pain immediately post partum, required less pain medication, had greater pelvic-floor muscle strength 3 months post partum, resumed sexual relations earlier, had less pain during sexual intercourse and were more satisfied sexually than any other group. Women with spontaneous perineal tears fared better than those who underwent episiotomy. After adjusting the results for reasons for requiring an episiotomy, we found that, among primiparous women in either arm of the trial, episiotomy was strongly associated with extension to third-degree or fourth-degree tears.

We noted that among some physicians in the trial many women they attended gave birth with an intact perineum and none had severe perineal trauma, whereas among other physicians no women they attended had an intact perineum, and as many as 20% to 30% of the primiparous women had severe perineal trauma. When we looked at physician compliance in caring for primiparous women we found that a third of the physicians did not change their use of episiotomy, as required by the study protocol; instead, they used episiotomy approximately 90% of the time for patients in both trial arms, and they failed to assign subjects randomly to one group or the other more often than physicians who complied. As well, physicians who did not comply with the protocol were more likely than those who complied to use oxytocin induction and augmentation of labour, epidural anesthesia and cesarean section. This was a

very different experience from that reported in a comparable British study, in which midwives in the restricted-use arm of the trial used episiotomy 10% of the time and those in the "liberal"-use arm used it 40% of the time.[3]

To understand what was behind this great difference in practice, we carried out a study to investigate what the physicians believed about episiotomy and perineal management and how these beliefs were related to their behaviour during the trial. We also studied the consequences of these beliefs and behaviours on perineal and other outcomes affecting the women involved in the study. Thus, for this analysis, we reanalysed the original data according to the attending physicians' beliefs about episiotomy, as determined with a questionnaire specifically developed for this purpose.

Methods

The methods used in the original trial have previously been described.[1,2] The study was a classic randomized controlled trial of management, analysed according to intention to treat. We enrolled women at 30 to 34 weeks of gestation who were to give birth at a university-affiliated tertiary care hospital serving primarily French-speaking patients or at one of two university-affiliated hospitals (one tertiary care and one community) serving primarily English-speaking patients in Montreal. The three sites served a population that is typical of Montreal. We present a post-hoc cohort analysis further analysed according to physician belief.

Study population

The 703 subjects originally enrolled attended the practices of 39 participating physicians. They were eligible for the study if they had a parity of 0, 1 or 2, were between 18 and 40 years of age, were carrying a single fetus, spoke English or French and had no apparent medical or obstetric risk factors. Physicians were recruited directly by the principal investigators. All of the physicians in the practice group of one investigator joined the study. Half the obstetricians and one family physician at the second hospital and 70% of the obstetricians and 80% of the family physicians at the third hospital were recruited. Since an additional four physicians covered the practices of some study physicians at one hospital, the actual number of participating physicians was 43. Since we had data on beliefs concerning episiotomy for only the 43 attending physicians, we selected only the 447 cases (226 primiparous and 221 multiparous subjects) in which the attending physician was present and was responsible for perineal management.

Outcomes

Immediately after birth, perineal and vaginal trauma was assessed, based on a predefined checklist. Perineal trauma was defined as sutured spontaneous tears of all types, including first-degree, second-degree, third-degree (into rectal muscle) and fourth-degree (through rectal muscle into the rectal mucosa) tears, as well as episiotomy and extension of episiotomy to third-degree or fourth-degree tears. Other outcomes studied were length of the first and second stages of labour, epidural anesthesia, use of forceps and cesarean section, position for birth, rate of and reasons for not assigning women to a study arm, perineal pain 1, 2 and 10 days post partum (measured on the McGill Pain Scale[4]) and the woman's satisfaction with the birth experience.

Establishment of categories of beliefs about episiotomy

Focus groups at a distant site (British Columbia's Women's Hospital, Vancouver) consisting of obstetricians, family physicians and midwives were interviewed to ascertain their views on the place of episiotomy in the care of women at no apparent risk and on the cause of severe perineal trauma. The responses were recorded on audiotape, and a content analysis was carried out. A questionnaire comprising 40 questions was developed and administered by mail to the participating trial physicians before they were aware of the results of the main trial.[1] The responses were scored on a four-point Likert-type scale from 1 (strongly agree) to 4 (strongly disagree). (The questionnaire is available from the authors on request.) No attempt was made to assess the validity and reliability of the survey instrument beyond its face validity. Information about demographic characteristics (age and sex) and practice characteristics (obstetrics or family practice and size of practice) was also collected.

Statistical analysis

We tested the comparability of the women cared for by the four quartiles (according to beliefs about episiotomy) of trial physicians using χ^2 tests, analysis of variance (ANOVA) or Kruskal–Wallis one-way ANOVA. The χ^2 test was used for nominal and categoric data and the ANOVA or Kruskal–Wallis ANOVA for ordinal and interval data. The same techniques were used to compare the physicians' demographic and practice characteristics. The reliability analyses were used to assess the internal reliability of the seven questions that constituted the final scale as well as the birth-satisfaction inventory.

We performed a multivariate linear regression analysis with the length of the first and second stages of labour,

Table 1: Statements used to establish beliefs about episiotomy among 43 physicians who participated in a randomized controlled trial of episiotomy

Statement	Quartile; mean score from 1 ("strongly agree") to 4 ("strongly disagree") (and standard deviation)*						
	Overall	VU	U	F	VF	*p* value†	Post-hoc tests‡
I regularly employ episiotomy to prevent perineal trauma	2.9 (0.9)	3.9 (0.3)	3.0 (0.4)	2.5 (1.0)	2.3 (0.9)	0.0001	VU > U, F, VF
I regularly employ episiotomy to prevent pelvic floor relaxation and the consequences of pelvic floor relaxation, such as bladder prolapse and urinary incontinence	3.3 (0.7)	4.0 (0.0)	3.5 (0.5)	2.9 (0.6)	2.8 (0.8)	0.0001	VU, U > F, VF
I prefer to employ episiotomy frequently, because it is easier to repair than the lacerations that result when episiotomy is not used	2.9 (0.9)	3.8 (0.4)	3.0 (0.8)	2.8 (0.8)	2.1 (0.8)	0.0001	VU > U, F > VF
Third-degree and fourth-degree tears are not a problem; I just suture them when they occur	2.0 (0.8)	2.7 (0.9)	1.7 (0.5)	1.9 (0.3)	1.5 (0.5)	0.0001	VU > U, F, VF
Third-degree and fourth-degree tears are an inevitable consequence of difficult delivery — largely due to maternal characteristics, fetal head size and position or features of the labour itself (such as use of epidural, forceps or other procedures)	2.3 (0.8)	3.0 (0.6)	2.5 (0.8)	2.1 (0.6)	1.8 (0.6)	0.001	VU, U > F, VF VU > U
The Ritgen or modified Ritgen manoeuvre§ is a significant contributing cause of third-degree and fourth-degree tears‖	2.2 (0.7)	2.8 (0.8)	2.2 (0.8)	2.0 (0.1)	1.7 (0.5)	0.001	VU > U, F, VF
Physicians who actively limit their use of episiotomy will cause a number of severe painful, anterior¶ tears	2.5 (0.8)	2.9 (0.7)	2.8 (0.8)	2.4 (0.7)	1.7 (0.5)	0.001	VU, U, F > VF
All seven statements** combined	2.6 (0.5)	3.3 (0.3)	2.7 (0.1)	2.4 (0.1)	2.0 (0.3)	0.0001	VU > U > F > VF

*One-way analysis of variance. Physicians viewed episiotomy very unfavourably (VU), unfavourably (U), favourably (F) or very favourably (VF).
†Degrees of freedom = 3, 41.
‡Student–Newman–Keuls procedure; significance level 0.05.
§A technique used at the end of the second stage of labour, at crowning, to expedite birth. It can lead to premature extension of the head and thus contribute to third-degree or fourth-degree tears.
‖Recoded for direction.
¶Periurethral or labial or both.
**Cronbach's $\alpha = 0.79$.

overall pain assessment and satisfaction with the birth experience as dependent variables. Multivariate logistic regressions were performed to identify relevant predictors of dichotomous outcomes (i.e., perineal outcomes). We used the following independent variables in the multivariate analyses: category of physician's beliefs (explained later), parity (primiparous v. multiparous) and group in the randomized trial (liberal use v. restricted use of episiotomy).

In view of the exploratory nature of this study as well as the absence of a hypothesis specified a priori, a two-tailed p value of less than 0.10 was accepted as the minimum criterion for significance. Power calculations were not appropriate because they had already been established for the original trial. The sample size was therefore predetermined. The data were analysed with the use of SPSS (version 4.0 for Macintosh, SPSS, Chicago, 1990) and StatView II (version 1.04, Abacus Concepts, Berkeley, Calif., 1991) software.

Results

All 43 physicians completed the questionnaire. The final scale was composed of seven questions (Table 1). These were selected because they displayed the greatest discrimination among respondents, each demonstrating a lack of consensus (median value 2.57 on the four-point scale) as well as a large standard deviation. Internal consistency (Cronbach's $\alpha = 0.79$) was obtained for the seven items, and each contributed significantly to the reliability of the scale. A physician with a high score on the scale was likely to view episiotomy and its consequences negatively. Conversely, a physician with a low score on the scale was likely to have a more favourable attitude toward episiotomy and its presumed benefits. On the basis of their scores, the physicians were then grouped into four quartiles according to whether they viewed episiotomy very unfavourably (VU), unfavourably (U), favourably (F) or very favourably (VF). Each quartile consisted of 11 physicians, except the F quartile, which had 10.

Table 2 shows selected demographic and practice characteristics of the four physician quartiles. Those who viewed episiotomy very favourably tended to be male and marginally older. Those who viewed the procedure very unfavourably had smaller practices. All six participating family practitioners and five obstetricians were in the group that viewed episiotomy very unfavourably.

The women cared for by physicians in the four quar-

Table 2: Selected characteristics of the physicians by belief quartile

Characteristic	Belief quartile VU *n = 11*	U *n = 11*	F *n = 10*	VF *n = 11*
Family physician, no. (and %)	6 (54)	0 (0)	0 (0)	0 (0)
Female, no. (and %)	4 (36)	2 (18)	5 (50)	1 (9)
Mean age (and standard deviation [SD]), yr	42 (7)	43 (6)	44 (8)	49 (12)
Mean no. of births per year (and SD)	117 (105)	315 (105)	217 (75)	209 (100)

Table 3: Selected characteristics of the 447 women originally enrolled in the study by physician belief quartile*

Characteristic	Belief quartile VU *n = 87*	U *n = 175*	F *n = 103*	VF *n = 82*
In restricted-use allocation group, no. (and %)	35 (40)	86 (49)	53 (51)	41 (50)
Primiparous, no. (and %)	38 (44)	93 (53)	51 (50)	44 (54)
Mean age (and SD), yr	28.8 (4.4)	29.4 (3.8)	29.7 (4.6)	29.0 (4.4)
Mean no. of years of schooling (and SD)	15.6 (3.4)	15.0 (3.1)	15.5 (2.7)	14.3 (2.9)
Mean height (and SD), m	1.65 (0.07)	1.64 (0.06)	1.64 (0.06)	1.64 (0.05)
Mean weight before pregnancy (and SD), kg	57.6 (8.1)	59.5 (9.3)	58.5 (8.0)	59.7 (9.6)
Mean weight gain (and SD), kg	15.5 (4.6)	15.0 (4.7)	14.5 (4.6)	14.5 (4.5)
Mean birth weight of babies (and SD), g	3447 (469)	3441 (431)	3434 (470)	3473 (517)
Mean gestational age of babies (and SD), wk	40 (12)	40 (12)	39 (11)	39 (12)

*Not all information was available for all of the women.

tiles were comparable in age, education, height, weight before pregnancy, weight gain, baby's birth weight and baby's gestational age (Table 3). Minor differences in parity and protocol tended to cancel each other out by leading to differences in episiotomy rates that went in opposite directions. We adjusted for these imbalances in the regression analysis.

Length of labour

The first stage of labour was 1 to 3.5 hours shorter for the women attended by physicians who viewed episiotomy more favourably (U, F and VF) than for those attended by physicians in the VU quartile ($p < 0.05$ for U and < 0.01 for VF) (Table 4). This difference was likely related to greater use of oxytocin augmentation by physicians in the U, F and VF quartiles. As expected, being in the liberal-use episiotomy protocol, along with multiparity, were associated with a shorter second stage, and multiparity with a shorter first stage.

Procedures

Of the procedures used (oxytocin induction and augmentation of labour, epidural anesthesia and instrumental delivery), only oxytocin augmentation was applied differently by the physicians in different quartiles. Logistic regression analysis showed two predictors of use of oxytocin augmentation that were of borderline significance: care by physicians in the U and F quartiles (odds ratios [ORs] 1.79 and 2.06 respectively, $p < 0.10$). As well, multiparity, as expected, was a very significant pre-

Table 4: Unstandardized coefficients for regression analyses of length of the first and second stages of labour by physician belief quartile, trial protocol and parity

	Dependent variables*	
Independent variable	Length of first stage of labour, h	Length of second stage of labour, min
Belief quartile†		
U	−2.34‡	6.29
F	−1.20	−2.04
VF	−3.48§	−4.66
Liberal-use allocation group‖	−0.92	−12.55§
Multiparity¶	−6.67§	−50.90§
Intercept	19.66	99.54
R^2	0.18	0.27

*n = 445 for first stage of labour and 444 for second stage of labour.
†Reference group: VU.
‡$p < 0.05$.
§$p < 0.01$.
‖Reference group: restricted-use allocation group.
¶Reference group: primiparity.

Table 5: Estimated odds ratios for use of oxytocin induction and augmentation of labour and use of lithotomy position by physician belief quartile, trial protocol and parity

	Odds ratio (OR) and 95% confidence interval (CI)	
Variable	Use of oxytocin augmentation	Use of lithotomy position
Belief quartile*		
U	1.79 (0.91–3.52)†	3.94 (2.27–6.83)‡
F	2.06 (0.99–4.27)†	4.55 (2.46–8.42)‡
VF	1.50 (0.68–3.28)	4.41 (2.31–8.43)‡
Liberal-use allocation group§	1.36 (0.87–2.13)	1.00 (0.68–1.50)
Multiparity‖	0.40 (0.25–0.63)‡	1.25 (0.84–1.85)

*Reference group: VU.
†$p < 0.10$.
‡$p < 0.001$.
§Reference group: restricted-use allocation group.
‖Reference group: primiparity.

dictor of reduced use of oxytocin augmentation (OR 0.4, $p < 0.001$) (Table 5).

Decision to assign women to study arms

The decision to randomly assign women enrolled in the study to liberal or restrictive episiotomy management was made late in labour. The decision not to assign the woman to a study arm was based on concerns for fetal or maternal well-being, reflecting the physician's overall view of birth and its risks. This decision was made more commonly by physicians in the three quartiles who viewed episiotomy more favourably (U, F and VF) than by those in the VU quartile, with the odds of such a decision in the F quartile being statistically significant (OR 1.88, 95% confidence interval [CI] 1.14 to 3.10) (Fig. 1). The ORs for the U and VF quartiles were 1.30 (95% CI 0.81 to 2.09) and 1.42 (95% CI 0.83 to 2.42) respectively.

Similarly, physicians in the U, F and VF quartiles gave "fetal distress" as a reason for not assigning women to study arms more often than did those in the VU quartile (OR 3.13 [95% CI 1.03 to 9.51] for the F quartile) (Fig. 1). The ORs for the U and VF quartiles were 2.33 (95% CI 0.78 to 6.99) and 2.57 (95% CI 0.80 to 8.26) respectively. Cesarean section was the reason for not assigning women to a study arm more often in the three quartiles of physicians who viewed episiotomy more favourably than among those in the VU quartile (OR approximately 1.5); however, the 95% CI for this result includes unity (0.74 to 3.04). As expected, multiparity reduced the chances of the woman not being assigned to a study arm for any reason (OR 0.25, 95% CI 0.15 to 0.40).

For subjects in the restricted-use arm, the physicians in the three quartiles who viewed episiotomy more favourably were more likely than those in the VU quartile to use episiotomy for the reasons "perineum not distensible" or "about to tear" (ORs 2.42 to 5.92, $p < 0.01$ for the F quartile and < 0.05 for the VF quartile) (Table 6). The differences between these same physician quartiles in this trial arm in the use of episiotomy because of "fetal distress" did not reach statistical significance; however, the trend was consistent with the other results. No infants in the study had low 5-minute Apgar scores and none was admitted to a special care unit.

Position for birth

The three quartiles of physicians who viewed episiotomy more favourably (U, F and VF) used the lithotomy position much more often than those in the VU quartile (ORs 3.94 to 4.55, $p < 0.001$) (Table 5).

Episiotomy rates

Physicians who viewed episiotomy unfavourably (VU and U quartiles) were able to change their behaviour according to the trial protocol instructions (Fig. 2). Those in the VU quartile were the most successful in limiting episiotomy use in the restricted-use trial arm, achieving results comparable to their British midwife counterparts.[3] Physicians who viewed episiotomy favourably (F and VF quartiles) had more difficulty following the protocol, with physicians in the F quartile actually using episiotomy more often in the restricted-use arm than in the liberal-use arm.

Perineal outcomes

Logistic regression analysis revealed significant pre-

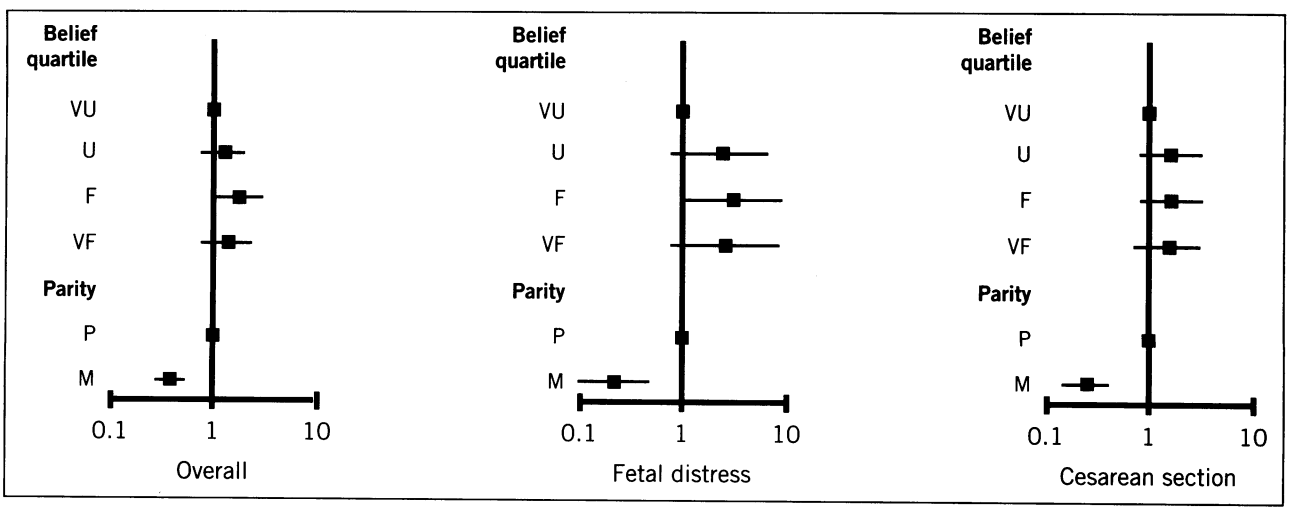

Fig. 1: Estimated odds ratios (black squares) and 95% confidence intervals (bars) for decision not to assign women to a study arm late in labour, overall and by reason, according to physician belief quartile and parity (n = 717). Physicians viewed episiotomy very unfavourably (VU), unfavourably (U), favourably (F), very favourably (VF). P = primiparity, M = multiparity.

dictors of an intact perineum following birth. Women cared for by physicians in the U and F quartiles were significantly less likely than women cared for by physicians in the VU quartile to have an intact perineum (ORs 0.45 and 0.43 respectively, $p < 0.05$) (Table 7). As expected, multiparous women were significantly more likely to have an intact perineum than were primiparous women (OR 3.85, $p < 0.001$).

Pain, and satisfaction with the birth experience

Multiple linear regression analysis for overall satisfaction with the birth experience (mean score on all 11 items combined; Cronbach's $\alpha = 0.87$) revealed two significant predictors of satisfaction. Women attended by physicians in the F and VF quartiles reported significantly lower levels of satisfaction than women attended by physicians in the VU quartile ($p < 0.01$) (Table 8). A similar trend was noted for the U quartile. Perineal pain was greater among women cared for by physicians in the VF quartile than among those cared for by physicians in the VU quartile ($p < 0.01$).

Discussion

We feel that, in our analysis, we have been able to situate episiotomy in a practice context. Physicians who viewed episiotomy very unfavourably used the procedure less often, and their patients had less severe perineal trauma (third-degree or fourth-degree tears), less perineal pain and higher levels of satisfaction with the birth experience than patients whose attending physicians viewed the procedure unfavourably, favourably or very favourably. Although the physician's quartile accounted for only 3% of the explained variance in overall satisfaction with the birth experience, it is unusual in studies of satisfaction with birth to see any differences in satisfaction levels among women who have healthy infants.

We have determined that physicians who use episiotomy frequently and routinely often do so as part of an interventionist pattern or style of practice. Episiotomy use, therefore, has provided a window on a system, beginning with physician beliefs and linking them directly to clinical actions and their consequences. Physicians who viewed episiotomy very unfavourably were more likely to allow labour to progress without interference, and women under their care had longer first stages of labour and received fewer oxytocin augmentations of labour and cesarean sections. Conversely, physicians who viewed episiotomy more favourably were more likely to see apparently normal labour as abnormal. They more often failed to open study envelopes in order to randomly assign women who, by the study definition, were similar to those attended by physicians in the VU quartile. As well, physicians who viewed episiotomy more favourably more often diagnosed fetal distress in apparently normal labours and more often thought the perineum was unable to distend or about to tear severely.

Our study is limited by its post-hoc nature. It is an exploratory and hypothesis-generating exercise that is con-

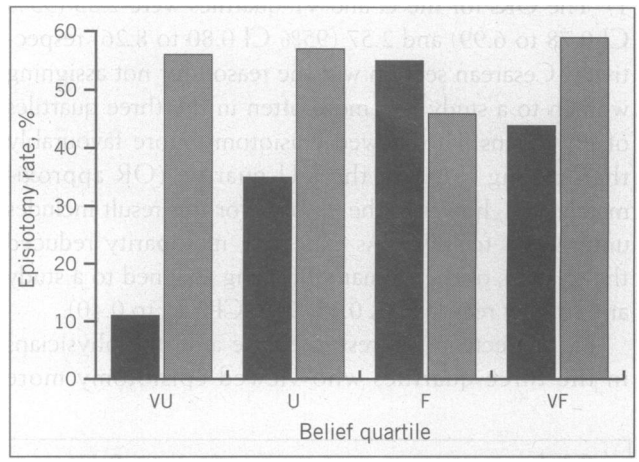

Fig. 2: Episiotomy rates among physicians in belief quartiles, by trial arm (restricted use [black bars] and liberal use [grey bars]).

Table 6: Estimated ORs for reasons for episiotomy in the restricted-use allocation group (n = 215) by physician belief quartile and parity

Variable	Reason; OR (and 95% CI)	
	Perineum not distensible or about to tear	Fetal distress
Belief quartile*		
U	2.42 (0.76–7.70)	4.20 (0.51–34.6)
F	5.92 (1.82–19.3)†	5.92 (0.70–50.39)‡
VF	4.36 (1.28–14.87)§	6.69 (0.77–58.24)‡
Multiparity‖	0.55 (0.30–1.02)‡	0.28 (0.11–0.74)

*Reference group: VU.
†$p < 0.01$.
‡$p < 0.10$.
§$p < 0.05$.
‖Reference group: primiparity.

strained by the relatively small number of physicians and women participating in the original trial, especially after births attended by residents and nurses were excluded. Therefore, the results cannot be generalized beyond the study settings. But if so many physicians who joined the trial voluntarily had such difficulty following the restricted-use protocol, it seems likely that other, less-motivated physicians may be expected to have similar or greater difficulty. Several of the outcomes were barely or not statistically significant, but in virtually all cases the direction of the difference between the physicians who viewed episiotomy very unfavourably and those in the other three quartiles was consistent and predictable. Thus, the pattern of less intervention overall among the physicians who viewed episiotomy very unfavourably is compelling. This consistency should help minimize statistical concerns that could not be overcome because of the largely descriptive and opportunistic nature of our study. We hope that the patterns reported here will encourage others to test the consequences of physician beliefs on outcome.

Although the reasons physicians fail to enter their patients in randomized controlled trials have been investigated,[5-7] little is known about physician behaviour during trials. The randomized controlled trial is the best method for evaluating therapeutic interventions.[8] However, successful trials of management are based on several assumptions. Central among these is the assumption of "clinical equipoise"; that physicians who agree to participate are sufficiently neutral with respect to the alter-

Table 7: Estimated ORs for perineal outcomes by physician belief quartile, trial protocol and parity (n = 447)

Variable	Perineal outcome; OR (and 95% CI)			
	Intact	First-degree or second-degree tear	Episiotomy	Third-degree or fourth-degree tear
Belief quartile*				
U	0.45 (0.22–0.91)†	0.85 (0.49–1.50)	1.45 (0.85–2.50)	2.33 (0.75–7.26)
F	0.43 (0.19–0.97)†	0.64 (0.34–1.22)	1.81 (0.99–3.29)‡	2.55 (0.77–8.51)
VF	0.55 (0.24–1.26)	0.61 (0.30–1.21)	1.80 (0.96–3.38)‡	2.20 (0.63–7.70)
Liberal-use allocation group§	0.69 (0.39–1.20)	0.53 (0.35–0.82)‖	2.14 (1.45–3.16)¶	0.84 (0.44–1.60)
Multiparity**	3.85 (2.07–7.15)¶	2.17 (1.42–3.32)¶	0.55 (0.38–0.81)‖	0.09 (0.03–0.24)¶

*Reference group: VU.
†$p < 0.05$.
‡$p < 0.10$.
§Reference group: restricted-use allocation group.
‖$p < 0.01$.
¶$p < 0.001$.
** Reference group: primiparity.

Table 8: Unstandardized coefficients for regression analyses of overall perineal pain and satisfaction with the birth experience by physician belief quartile, trial protocol and parity

Variable	Dependent variables*	
	Overall perineal pain†	Overall satisfaction‡
Belief quartile§		
U	0.11	−1.09‖
F	0.01	−2.11¶
VF	0.23¶	−1.91¶
Liberal-use allocation group**	−0.04	−1.58
Multiparity††	−0.37‡‡	−0.03
Intercept	1.18	40.46
R^2	0.12	0.03

*n = 441 for overall perineal pain and 426 for overall satisfaction.
†Mean pain score (measured with the McGill pain scale[4]) 1, 2 and 10 days post partum.
‡Mean score on 11 items (Cronbach's $\alpha = 0.87$).
§Reference group: VU.
‖$p < 0.10$.
¶$p < 0.01$.
** Reference group: restricted-use allocation group.
††Reference group: primiparity.
‡‡$p < 0.001$.

native strategies: they will enrol only study subjects who meet the inclusion criteria, they will enrol study subjects representative of those who may benefit from the intervention, they will randomly assign subjects often enough, they will avoid bias in the decision concerning which patients are appropriate for allocation by using criteria specified in the protocol and they will comply with the management strategy of the designated study arm once the subject is entered in the trial. If these assumptions are incorrect, an otherwise well-constructed randomized controlled trial may be threatened, leading to an ungeneralizable study, to the loss of adequate statistical power to answer the question, to the introduction of hidden biases or to a narrowing of the difference in the rates of the two interventions, thereby reducing the trial's ability to detect outcome differences.

In our original trial comparing two approaches to median episiotomy[1] we encountered several of these problems. Since we were studying a well-established procedure, we could have realized that resistance to the experimental manoeuvre would be common. We enrolled 20% of subjects eligible by obstetric criteria. We expected physicians to decide not to assign subjects to study arms at a rate of 30% and obtained a rate of 33%; however, we found unexpected variation between physicians in the rate of random allocation of comparable subjects. After random assignment, the high level of episiotomy use (noncompliance) in the restricted-use arm of the study was unexpected. But, since we had enough trial subjects, the study was, with difficulty, sustained. In fact, the noncompliant physicians provided us with important information on what lay behind their resistance, which in turn allowed us to situate episiotomy within a larger explanatory framework.

Information on the relation of attitudes and beliefs to care and outcome is only beginning to accumulate,[9–18] and only a little is known about the relation of episiotomy use to attitudes.[19,20] Our results are compatible with those found in the literature on small-area variation[21,22] and specifically in studies on the determinants of cesarean section;[10–15] but they may be unusual in linking several procedures to demonstrate a pattern or style of practice based on defined beliefs.

We feel that clinical trials based on differences in management should take into consideration the belief system of the participating physicians. Otherwise, such trials may fail without the investigators' being aware of the reason for the failure. Furthermore, the Dr. Roger Poisson affair in the trial of mastectomy versus lumpectomy for the treatment of breast cancer has shown the dangers to the experimental manoeuvre when participating physicians deviate from clinical equipoise or misunderstand the essential features of the clinical trial. Since this type of practice-based management trial is common, we urge the development of methods for building information about physicians' beliefs into trials. This should enable quantitative data from the principal trial to be complemented by qualitative and semiquantitative information that allows a greater understanding of what underlies the actions of participating physicians. This could lead to a decision to randomly assign physicians rather than patients, or at least to stratify physicians or otherwise control for this factor.

The process of changing physicians' practices is never easy,[23–25] especially when it appears that many approaches are interconnected. Developing an understanding between women and those attending their labour and delivery, based on the realization that an intact perineum is the preferable, and third-degree or fourth-degree tears the least desirable, outcome, and that spontaneous tears appear preferable to episiotomy, may set the stage for a more open dialogue between women and their birth attendants. This step may help move the process of choice closer to one in which women feel they have control of their labour and delivery and feel more satisfied with the experience.

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